MAR 1 2013

510(k) Summary – Uni-Gold™ Giardia

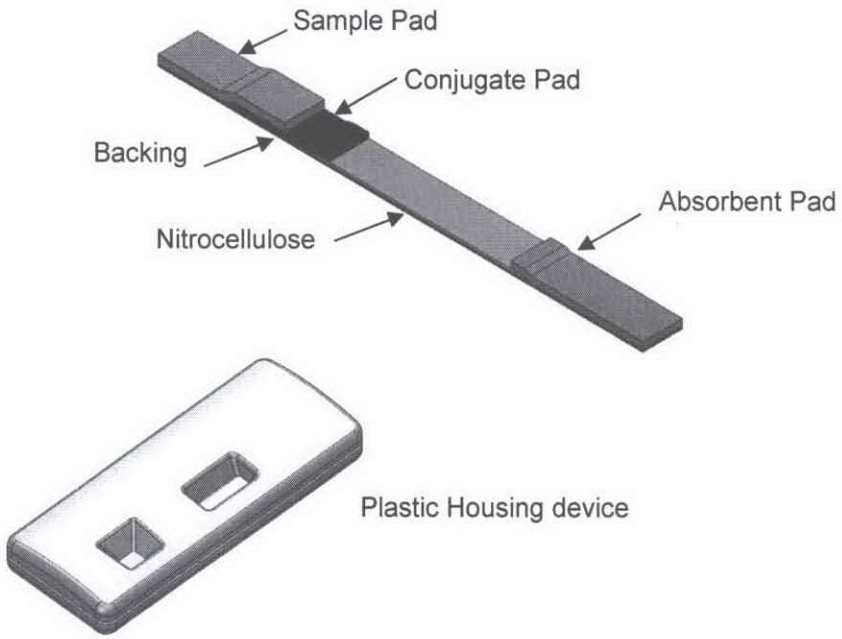
510(k) Number Assigned:	K120001
Introduction:	Trinity Biotech hereby submits this 510(k) summary for the Uni-Gold™ Giardia Rapid Lateral Flow Test Kit in accordance with the requirements of 21 CFR 807.92(C).
Submitter's Identification: Name & Address:	MarDx Diagnostics, a Trinity Biotech Company, 5919 Farnsworth Ct. Carlsbad, CA. 92008, USA.
Contact:	Contact Person: Bonnie DeJoy, Corporate VP of RA (Official Correspondent) Email: Bonnie.DeJoy@TrinityUSA.Com Address: 2823 Girts Road Jamestown, NY 14701 Phone: 716-483-3851 Extension 1030 Fax: 716-488-1990
Date Summary Prepared:	February 21, 2013
Device Trade Name:	Uni-Gold™ Giardia
Classification Name:	*Entamoeba histolytica* serological reagents. Giardia SPP 866.3220 Code MHI
Classification Product Code:	MHI
Intended Use:	Trinity Biotech Uni-Gold™ Giardia is a single use rapid immunoassay for the qualitative detection of *Giardia lamblia (G. lamblia)* antigens in human stool specimens. This test is intended for use with patients with gastrointestinal symptoms as an aid in the diagnosis of suspected *Giardia* gastrointestinal infections. As with other *Giardia* tests, results should be considered in conjunction with the clinical evaluation and medical history. For *In-Vitro* Diagnostic use.
Predicate Device	Remel Xpect™ Giardia Lateral Flow Assay (510K #: K031942)

Device Description

The Trinity Biotech Uni-Gold™ Giardia was designed as a single use, rapid, lateral flow immunoassay test device to detect the presence of *Giardia lamblia* antigen in unpreserved (fresh & frozen), preserved and media containing human stool specimens.

The Trinity Biotech Uni-Gold™ Giardia test strip (5mm x 60mm) combines a Nitrocellulose Membrane with designated fiber pads (conjugate, sample and absorbant). The test strip is then placed into a plastic housing and is sealed constituting the Test Device.

Picture A- Giardia Test Strip - 5 mm x 60 mm



The Giardia Nitrocellulose Membrane Test Strip - above consist of

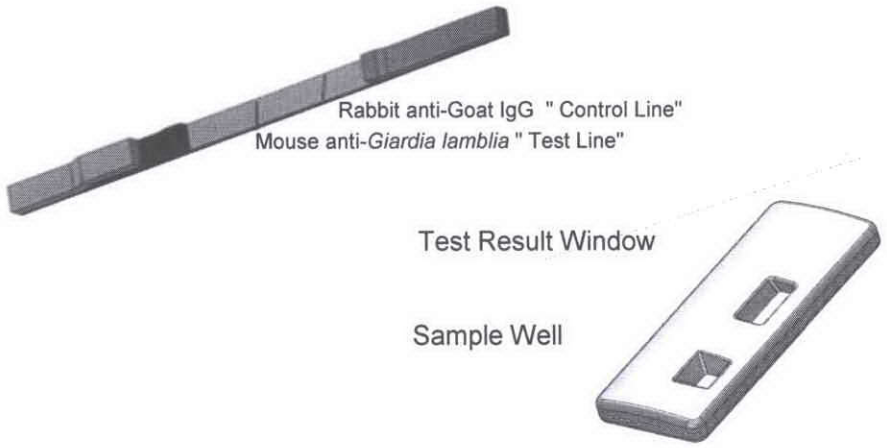
A) Mouse anti-*Giardia lamblia* antibody is coated onto the Test Line region of the test strip.

B) Rabbit anti-Goat IgG antibody is coated onto the Control Line region of the Test Strip.

C) Goat anti- *Giardia lamblia* antibodies and Goat IgG antibodies are conjugated to red latex particles and dried onto the inert glass fiber (Conjugate Pad) which is inserted into the test strip below the nitrocellulose zone.

When Giardia antigens are present in the sample they combine with the antibody/red latex complex. As the complex migrates it binds to the antibodies in the test region forming a visible pink/red band. ***(Picture B)*** This forms the basis for the double antibody sandwich assay. Excess conjugate forms a second pink/red band in the control region of the device. The control line should always appear as a visible pink/red band in the control region of the device. This internal control line is to ensure and indicate that the test device is functioning correctly.

Picture B- Giardia Test Device



The plastic housing device contains a window where the diluted stool sample is added (Sample Well) and a window above where the results are read in 15 minutes.

The test concept:

Mouse anti-*Giardia lamblia* is coated onto the test line region of the nitrocellulose zone of the test strip. Rabbit anti- Goat IgG is coated onto the control line region.
Goat anti-*Giardia lamblia* antibodies are conjugated to red latex particles and dried onto inert glass fiber. This is inserted into the test strip below the nitrocellulose zone.

A buffered solution is added to a dilution tube followed by the addition of the stool specimen (2 drops) via a disposable pipette. This mixture is then dispensed in total into the sample well of the lateral flow cartridge device with a dropper pipette and migrates through a pad containing red microspheres that have been coated with a antibody specific for the Giardia antigen. If the antigen is present, an immune complex forms. The migration continues along the membrane, which contains a striped down anti *Giardia* capture antibody. If Giardia antigen is present, the immune complex reacts with the anti-*Giardia* antibody at the test line on the membrane.

Thus Giardia antigens present in the sample combine with the antibody/red latex. As this complex migrates it binds to the antibodies in the test region forming a visible pink/red band.

Excess conjugate forms a second pink/red band in the control region of the device. The control line should always appear as a visible pink/red band in the control region of the device to indicate that the test device is functioning correctly.

Comparison with Predicate Device

The predicate device and Uni-Gold™ Giardia use similar lateral flow technology and concepts. The following table provides a comparative summary for both device design features. Any differences in technology do not raise additional concerns regarding safety and effectiveness. Safety and effectiveness are demonstrated to be substantially equivalent.

Aspect or Feature		
Comparison Table		
	(Remel -K031942)	**Trinity Biotech Uni-Gold™ Giardia**
Intended Use	Detection of Giardia antigens in fecal specimens.	Detection of Giardia antigens in stool (fecal) specimens.
Technology	Qualitative immunochromatographic assay	Qualitative immunochromatographic assay
Capture antibodies on membrane	Rabbit anti-Giardia, goat anti- mouse IgG	Mouse anti-Giardia lamblia, Rabbit anti-Goat IgG
Material: Membrane	Mylar-backed Nitrocellulose	Nitrocellulose
Conjugate antibodies	Monoclonal anti-Giardia, Normal Mouse IgG	Goat anti-Giardia lamblia, Goat IgG antibodies
Material Conjugate:	Anti-Giardia and mouse IgG colored polystyrene particles diluted in buffer	Anti-Giardia and Goat IgG colored latex dried onto conjugate pad
Specimen Types	Human Stool preserved in 10% formalin, SAF,or Cary Blair	Human Stool: Fresh/Frozen, preserved (10% formalin or SAF) or provided in Cary Blair, or C&S Transport Medium
Sample volume	100 µl	2 drops- approximately 40-60µl

Precision / Reproducibility

An Intra-run precision/reproducibility study was performed at 3 sites including one internal site. This study consisted of 6 blind proficiency panel members, varying in reactivity: (2) Low Positive, (2) High Positive and (2) Negative samples. This panel was tested for a period of 5 days. Each site generated 2 runs per day, by two individual technicians totaling 20 replicates per site per panel member, i.e.12C replicates total. 100% reproducibility was observed for all sites, for all days using the blind panel sample set, therefore 100% of the 120 samples tested for Giardia produced the expected result.

An additional Intra-run precision/reproducibility study was performed internal internally. This study consisted of 12 blind proficiency panel members, varying in reactivity: (4) Low Positive, (4) High Positive and (4) Negative samples. This panel was tested for a period of 5 days. Each site generated 2 runs per day, by two individual technicians totaling 20 replicates per panel member. 100% reproducibility was observed for all days using the blind panel sample set, therefore 100% of the samples tested for Giardia produced the expected result.

Percent Correlation

The Trinity Biotech Uni-Gold™ Giardia (1206610) along with Uni-Gold™ Giardia Control kit (1206611) was evaluated at 3 external laboratories. A total of 267 retrospective samples were tested side by side on the test device and a commercially available lateral flow device at three external sites in the following stool matrix types: unpreserved frozen (42), C&S (15), SAF (139), and formalin (71).. The percent agreement of Uni-Gold™ Giardia versus the comparator device was as follows:

Site 1	Giardia	Comparator Device		% Agr
		+	-	
Uni-Gold™	+	26	3*	100% Pos Agr
	-	0	48	94.1% Neg Agr

Site 2	Giardia	Comparator Device		% Agr
		+	-	
Uni-Gold™	+	51	0	100% Pos Agr
	-	0	49	100% Neg Agr

Site 3	Giardia	Comparator Device		% Agr
		+	-	
Uni-Gold™	+	54	6**	100% Pos Agr
	-	0	30	83.3% Neg Agr

* At Site 1, the 3 samples that tested positive on Uni-Gold™ Giardia and negative on the comparator device were positive by DFA microscopy in agreement with the Uni-Gold™ Giardia result.

**At Site 3, the 6 samples that tested positive on Uni-Gold™ Giardia and negative on the comparator device were positive by Iron Hematoxylin Stain

microscopy in agreement with the Uni-Gold™ Giardia result.

Cross Reactivity

No cross reactivity was observed using samples containing the following organisms: *Adenovirus serotypes 3, 5, 7, 40, 41, Aeromonas hydrophila, Ascaris lumbricoides, Bacteroides fragilis, Bacillus cereus, Bacillus subtilis, Blastocystis hominis, Campylobacter coli, Campylobacter fetus, Campylobacter jejuni, Candida albicans, Chilomastix mesnili, Clostridium difficile, Clostridium biffermentans, Coronavirus OC43, Coxsackievirus, Cryptosporidium parvum, Cyclspora cayetanensis, Cytomegalovirus (CMV), Dientamoeba fragilis, Diphyllobothrium latum, Echovirus 20, Endolimax nana, Entamoeba coli, Entamoeba hartmanni, Entamoeba histolytica, Enterobius vermincularis, Enterococcus faecalis, Escherichia coli, Escherichia coli 0157H7, Hookworm, Hymenolepis nana, Iodamoeba butschlii, Isospora sp., Klebsiella pneumoniae, Microsporidia, Salmonella typhimurium, Shigella dysenteriae, Shigella flexneri, Shigella sonnei, Staphylococcus aureua, Staphylococcus aureus (Cowan's), Staphylococcus epidermidis, Strongyloides stercoralis, Taenia sp., Trichurius trichiura, Vibrio parahaemolyticus, and Yersinia enterocolitica.*

Cross Reactivity has not been established for *E. dispar.*

Interfering Substance

The analytical specificity of the test was determined in stool samples containing potentially interfering substances at clinically relevant concentrations. Compounds were respectively spiked into positive and negative samples at medically relevant dosages (treatment). All treatments, including the unspiked (neat) positive and unspiked (neat) negative samples were tested in duplicate with Uni-Gold™ Giardia. The following compounds were tested: Human blood (20% v/v), Mucin (10% w/v), Stool fat (Triglycerides 0.14mg/ml or Stearic Acid 20% v/v), Pepto-Bismol (Bismuth) (20% v/v), Imodium A-D (Loperamide HCl) (20% v/v), Kaopectate (Attapugite) (20% v/v), Vancomycin (0.6mg/ml), K-Y jelly (0.289mg/ml), Vasoline (0.22mg/ml), Condom lubricant (1.716mg/ml), Maalox (magnesium hydroxide, calcium carbonate) (20% v/v), Tagamet (Cimetidine) ($2.0x10^{-2}$ mg/ml), Pepsid (Famotidine) ($6.0x10^{-4}$ mg/ml), Zantac (Ranitidine) ($6.0x10^{-3}$ mg/ml), Prilosec (Omeprazole) ($6.0x10^{-3}$ mg/ml), Nitrazoxanide ($6.96x10^{-3}$ mg/ml), Atovaquone (0.031mg/ml), Azithromycin ($1.2x10^{-2}$ mg/ml), Metronidazole (0.12mg/ml), Paromomycin (0.42mg/ml), Trimethoprim-sulfamethoxazole (TRM 0.04mg/ml & Sulf 0.4mg/ml). No test interference was observed by any of the compounds at the concentrations tested.

Sensitivity/ Specificity

The Trinity Biotech Uni-Gold™ Giardia (1206610) along with Uni-Gold™ Giardia Control kit (1206611) was evaluated at 4 external laboratories. The sensitivity and specificity of the test was compared against DFA microscopy with retrospective samples at sites 1 and 2 as shown in the following table.

Giardia			DFA Microscopy	
			+	-
Site 1	Uni-Gold™	+	37	0
		-	0	117
Site 2	Uni-Gold™	+	54	0
		-	0	33
Total	Uni-Gold™	+	91	0
		-	0	150

Sensitivity: 100% (91/91) 95%CI 95 – 100%
Specificity: 100% (150/150) 95%CI 97 – 100%

The positive samples were tested in the following matrix types: formalin (48), SAF (13), unpreserved frozen (17), Cary Blair (3), and C&S (10). The negative samples were tested in the following matrix types: formalin (42), SAF (70), unpreserved frozen (25), Cary Blair (3), and C&S (10)

Additional retrospective studies
Performance of the test was compared to non-fluorescent microscopy (staining) at two external laboratories. At site 2, 67 retrospective samples were evaluated and demonstrated a Positive Percent Agreement (PPA) of 100% (22/22) and a Negative Percent Agreement (NPA) of 100% (45/45) versus Wheatley's Stain. At site 3, 259 retrospective samples were evaluated and demonstrated a PPA of 100% (60/60) and aNPA of 100% (199/199) versus Iron Hematoxylin Stain.

Prospective Study
The following table shows a summary of test performance compared against DFA microscopy with prospective samples at site 4.

Site 4	Giardia		Giardia DFA	
			+	-
	Uni-Gold™	+	0	0
		-	0	378

Specificity: 100% (378/378) 95% CI 99 – 100%

Due to infection prevalence, no positive samples were encountered during this prospective study. Samples were tested in the following sample matrix types: unpreserved fresh (153), unpreserved frozen (45), formalin (45), SAF (45), C&S (45), and Cary Blair (45).

Expected Values
The performance of the Uni-Gold Giardia™ Test Kit was evaluated at four external laboratories. The 945 (prospective and retrospective) samples were collected from Hospitals throughout the US and Canada and consisted of both male and female patients, of all ages from pediatric to adult, who presented with gastrointestinal symptoms. The retrospective study included 173 positive samples and 394 negative samples confirmed by microscopy. The prospective study included 378 samples which were subsequently confirmed negative by microscopy. There were no differences observed in clinical performance between

	males or females, or between pediatric or adult populations.
Substantial Equivalence conclusion	The information submitted in this premarket notification is complete and supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Trinity Biotech
C/O Bonnie DeJoy
5919 Farnsworth Ct.
Carlsbad, CA 92008

March 1, 2013

Re: K120001
Trade Name: Uni-Gold™ Giardia
Regulation Number: 21 CFR 866.3220
Regulation Name: *Entamoeba histolytica* serological reagents
Regulatory Class: Class II
Product Code: MHI
Dated: February 22, 2013
Received: February 25, 2013

Dear Ms. DeJoy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K120001

Device Name: ***Uni-Gold™ Giardia***

Indications for Use:

Trinity Biotech Uni-Gold™ Giardia is a single use rapid immunoassay for the qualitative detection of *Giardia lamblia (G. lamblia)* antigens in human stool specimens. This test is intended for use with patients with gastrointestinal symptoms as an aid in the diagnosis of suspected *Giardia* gastrointestinal infections. As with other *Giardia* tests, results should be considered in conjunction with the clinical evaluation and medical history. For *In-Vitro* Diagnostic use.

Prescription Use ____√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Vitro Diagnostic Devices (OIVD)

Raquel A. Peat -S
2013.02.28 15:00:03 -05'00'

Division Sign -Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(K) K120001